DEPARTMENT OF HEALTH AND HUMAN SERVICES 95020d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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October 4, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED **Refer to MIN 05 – 02**

Jeffrey E. Grimmer
Grimmer Enterprises
R.R.2, Box 127
North Mankato, Minnesota 56003

Dear Mr. Grimmer:

On July 22, 2004, an investigator with the United States Food and Drug Administration (FDA) collected a sample of American Ginseng capsules from you. You informed the investigator that you had purchased the Ginseng from Shang Gardens, Inc., and that you then market it on the Internet. The 50 count bottles of American Ginseng capsules that were collected from you were labeled, in part, "MFG. SHANG GARDENS" and the lot number was identified as 110154. The label identifies this product as a dietary supplement and, as such, it is a food within the meaning of Sections 201(f) and 201(ff) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. 321(ff)]. You can find the Act on the Internet through links on FDA's web page at www.fda.gov.

Our review of your labeling for your American Ginseng product found on your website at http://www.shanggardens.com revealed that you made claims that cause your product to be a drug under the Act. Labeling is not limited to the immediate product container but, as defined in Section 201(m) of the Act [21 U.S.C. 321(m)], includes all promotional material you distribute in connection with your products.

Specifically, we have determined that your American Ginseng product is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act ("the Act") [21 U.S.C. 321(g)(1)(B)]. The therapeutic claims on your website establish this product as a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. Examples of some of the claims observed on your website include:

1. Under the icon for "what is american ginseng?"
   Your website states, "[g]inseng has been shown to...lower cholesterol,

prevent infections,...aid in cancer treatment, arthritis and impotency to name a few cases."

2. Under the icon for "key benefits of ginseng use"
   A. Your website states, "cardiovascular health...restore blood pressure after shock and heart attacks." "[r]eport that ginseng helps to reduce high blood pressure." "[S]everal studies suggesting that ginseng reduces cholesterol in the circulation." "American ginseng is the most successful at lowering cholesterol levels..."
   B. Your website also states, "Prevent infections..." "Cancer Treatment." "[S]tudies have shown that patients given a regular dose of ginseng were able to better cope with increased anti-cancer drugs."
   C. It further states, "Diabetes...it has an effect on diabetes..." "It has also lowered blood sugar levels..."
   D. In addition, it states, "[D]octors noticed striking improvements when using ginseng in the treatment of patients suffering form impotence."
   E. Finally, your website states, "[H]elps to treat cardiovascular diseases..." "[G]enseng reduces their arthritis substantially. One gentlemen was so crippled up with arthritis he was unable to climb to his deer hunting stand. After taking ginseng for some period of time, he described his arthritis as being 80% gone."

Furthermore, FDA has no information that your American Ginseng product is generally recognized as safe and effective for the above-referenced conditions and therefore, the product may also be a "new drug" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements or as cosmetics if therapeutic claims are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act (DSHEA), dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain conditions are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be

established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at http://vm.cfsan.fda.gov/~lrd/fr000106.html [codified at 21 C.F.R. 101.93(g)].

In addition, the Ginseng capsules were analyzed by FDA to determine compliance with the Act. Analysis of the capsules found pesticide chemicals for which no tolerance levels have been established. As a result, the product constitutes an article of food that was adulterated when introduced into and while in interstate commerce, and was adulterated while held for sale after shipment in interstate commerce, within the meaning of Section 402(a)(2)(B) of the Act [21 U.S.C. 342(a)(2)(B)]. The article bears and contains pesticide chemical residues, namely Pentachlorobenzene, Quintozene, Pentachloroaniline and Lindane, that are unsafe within the meaning of Section 408(a) of the Act [21 U.S.C. 346a(a)], because no tolerance or exemption from the requirements of a tolerance is in effect for the pesticide chemical residue on the article of food.

This letter is not intended to be an all-inclusive review of your website and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. Failure to do so may result in regulatory action, without further notice, such as seizure and/or injunction. You should notify this office, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. You should direct your reply to Compliance Officer Jane Nelson at the address on the letterhead. She may be reached at (612) 758-7119 if you have any questions.

Sincerely,

W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District

JEN/ccl

xc: Dean E. Budde
President
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